REMARKS

A. Terminal Disclaimer

Without admission that the present claims are obvious in view of the claims of the cited patents of assignee, and to expedite allowance of the present application, a terminal disclaimer is submitted herewith with respect to all patents cited as a basis for double patenting rejection in pages 5–7 of the Office Action.

Declaration of Paul J. Buscemi, Ph.D.

In support of this amendment, a declaration is submitted by Paul J. Buscemi, Ph.D. Dr. Buscemi has a doctorate in biomaterials and has many years of experience in research and development in biomaterials with a heavy emphasis in studying and evaluating tissue response (including fibrosis) to implanted materials. Throughout these Remarks, reference is made to various portions of the Buscemi Declaration.

B. Discussion of Cited References

1. German Patent DE 44 12 190 A1 ("Schreiber")

Schreiber was cited to reject claims 1, 4 – 9, 11 and 12. Since a flowable medium (such as the injected collagen of Schreiber) has little mechanical strength to impart to tissue, Applicants do not believe Schreiber anticipates these claims. Nevertheless, to expedite allowance, Applicants amends independent claim 1 to recite the implant is a solid of pre-formed dimensions.

The text of Schneider (including claims) clearly indicates Schneider is referring to injection of flowable, injectable collagen and not a solid of preformed dimensions. Specifically, in addition to repeatedly stating the substance is "injected" (by itself indicating a flowable substance), Schneider states the collagen "is injected successively and beginning with small doses while observing the change of the voice" (emphasis added). (Buscemi Declaration, ¶ 7.b.).

The present invention pertains to a solid implant. The implant is clearly identified as a solid implant having pre-formed dimensions (i.e., not a flowable substance).

It would not be obvious to modify Schneider to be a solid. Schneider is clearly concerned with avoiding vocal effects from over-stiffening the palate. Therefore, Schneider

begins injection of the flowable substance in small doses. Vocal effects are observed. If there are no adverse vocal effects, a second dose is administered and the process is repeated.

Therefore, Schneider teaches away from a solid pre-formed implant since Schneider wants to control the process with progressive doses. As a result it would not be obvious to alter Schneider to a solid implant since such an alteration deprives Schneider of the dose control deemed essential by Schneider.

Schneider is more similar to sclerosing therapy treatments of the soft palate. In these procedures, a fluid, flowable sclerosing agent is injected into the soft palate to create a scar. Such a treatment is described in LaFrentz et al., "Palatal Stiffening Techniques for Snoring in a novel Canine Model", Abstracts of the Twenty-Second Annual MidWinter Meeting of the Association for Research in Otolaryngology, Abstract No. 499, Vol. 22, pp. 125 – 126 (February 13 – 18, 1999) (cited in Applicants Information Disclosure Statement submitted with the filing of the present application).

2. U.S. Pat. No. 5,979,456 ("Magovern")

Magovern was cited to reject claims 1, 2, 6 – 10 and 12. Independent claim 1 is amended to more clearly distinguish over Magovern to expedite allowance. These amendments include reciting the implant is a passive implant acting without application of external energy. Further, relevant amendments include identifying the material of the implant inducing a fibrotic response of material amount.

a. Magovern Requires Activation By An Energy Source to Alter Physiology

The Examiner has directed Applicants' attention to the embodiments of Figs. 8 – 10. The Examiner will recognize that Magovern is an active implant which only functions when activated. This activation is heating or cooling to alter the crystalline structure of the material of Magovern. (Buscemi Declaration, ¶ 5.b.).

Independent claim 1 is are amended to clearly recite the alteration of tissue response is passive and does not require an activation force.

b. Magovern Does Not Teach A Material Which Imparts A Fibrotic Sufficient When Combined With Passive Mechanical Stiffness to Alter Physiology

i. There is No Evidence Supporting a Conclusion that Fibrosis is Inherent

Applicants' do not agree with the Examiner's statement on page 3 of the Office Action, (with respect to claim 6, now canceled in view of amendments to claim 1), that "the material implanted would inherently induce at least some fibrotic response in said soft tissue" (emphasis added). This statement of inherency is made without supporting facts or technical reasoning as required by M.P.E.P. Section 2114 IV which states "'In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.'" Quoting *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (Emphasis original). Further, one of ordinary skill in the art would recognize that any fibrosis is *di minimus* and would not be in an amount sufficient to alter tissue response or materially stiffen tissue. (Buscemi Declaration, ¶ 5.c and 5.d).

ii. Even Magovern Were to Have Some Stiffness, It would Be Inadequate to Materially Alter Tissue Stiffness

Moreover, Applicants note the present claims do not recite "at least some fibrotic tissue response". Instead, the claim 1 now recites the fibrotic response is sufficient in combination with the passive mechanical characteristics (e.g., stiffness) of the implant to alter tissue response to airflow. In Magovern, the implanted device only affects physiology when activated by an energy source (as already noted by the Examiner). Neither the passive material qualities, any fibrotic response, nor any combination of mechanical stiffness and fibrosis is adequate in Magovern to alter tissue stiffness. (Buscemi Declaration, ¶ 5.c and 5.d).

The implants of Magovern are described as one or more suture-like threads of shape-memory material inserted into musculature. (Magovern, col. 7, lines 56 – 59). The shape-memory material is described in column 5, lines 48 – 56. Suture-like threads of such material in musculature do not have a significant fibrotic response. Furthermore, such materials are highly

compliant such that the material strength and any miniscule fibrotic response would not alter tissue response to airflow. (Buscemi Declaration, ¶ 5.c and 5.d).

3. **U.S. Pat. No. 6,106,541 ("Hurbis") and U.S. 5,752,934 ("Campbell")**

Hurbis was combined with Campbell to reject claims 1, 2, 6 – 8, 11 and 12. These claims are amended to more clearly distinguish over Hurbis to expedite allowance even though Applicants believe that, as filed, Hurbis does not anticipate the claims. Particularly, amendments to claims include reciting the implant as being formed of a material selected to induce fibrosis of a material amount. It would not be obvious to substitute the PTFE braid of Campbell for the material of Hubris since Hubris teaches away from such combination.

Hurbis intentionally selects a material for avoiding a fibrotic response. The structure of the Hubris nasal dilator 10 is shown in Fig. 4 in cross-section and includes an internal skeleton structure 24and an external encasing sheath 26. The encasing sheath 26 "must consist of a material that is biocompatible when implanted into the face. Suitable materials include expanded polytetrafluroethylene [sic] (PTFE) materials ...". (Hubris, col. 3, line 65 through col. 4, line 1). Hubris lauds the safe historical use of such material in implants for the face. (Hubris, col. 4, lines 1 – 11). Those skilled in the art will recognize that expanded polytetrafluoroethylene is very low fibrosis-inducing material. (Buscemi Declaration, ¶ 6.c). Hurbis teaches away from a material selected to induce fibrosis. Therefore it would not be obvious to combine Hubris and Campbell. (Buscemi Declaration, ¶ 6.d.).

Moreover, Hurbis would want to avoid fibrosis to avoid adverse cosmetic effects. The implant of Hurbis is just beneath the skin and overlying cartilage or bone. Fibrosis would result in bulking which would have an adverse cosmetic appearance on the nose. (Buscemi Declaration, ¶ 6.a).

F. Supplemental Information Disclosure Statement

Submitted herewith is a supplemental Information Disclosure Statement citing the Ersek article which was cited in a related application. It is believed the teachings of Ersek are no more material than those already considered by the Examiner.

G. Conclusion

Applicants submit this application is now in condition for allowance. Reconsideration and Notice of Allowance are solicited. If the Examiner believes a telephone conference would

advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: December 22, 2005

Timothy R. Conrad
Reg. No. 30,164
TRC:PLSkaw